BlueCross BlueShield Association

An Association of
Independent Blue Cross
and Blue Shield Plans

1310 G Street, N.W.
Washington, D.C. 20005
Telephone 202.626.4780
Fax 202.626.4833

September 19, 2000

Dr. Jane Henney
Commissioner of Food and Drugs
c/o Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: FDA Draft Guidance for Industry: "Content and Format of the Adverse Reactions Section of Labeling for Human Prescription Drugs and Biologics"
Docket No. 00D-1306
65 Fed. Reg. 38563 (June 21, 2000)

Dear Commissioner Henney:

The Blue Cross and Blue Shield Association (BCBSA) appreciates the opportunity to submit these comments on the draft guidance for industry published by the FDA on June 21, 2000, concerning the content and format of the adverse reactions section of drug and biologics labeling.

BCBSA represents the 47 independent Blue Cross and Blue Shield Plans that provide health care financing and delivery to 77 million people – approximately one in four Americans. Blue Cross and Blue Shield Plans have extensive experience in providing prescription drug coverage through a variety of products.

BCBSA shares the FDA's goal of ensuring that health care professionals and consumers receive clear, accurate and meaningful information from manufacturers about the risks and benefits of prescription drugs. We believe that the format and content changes outlined in the FDA's draft guidance generally represent a positive step forward toward achieving this goal and we applaud the agency for addressing this important issue.

In particular, BCBSA support the FDA's effort to ensure that manufacturers avoid the use of subjective and vague terms to characterize an adverse reaction. We agree that if terms such as "rare," "infrequent," and "frequent" are used, that their use should be consistent with their regulatory definitions found in 21 CFR §201.57(g)(2).

We do ask that you consider three issues stemming from the guidance:

a. The impact of adverse reaction labeling on consumer safety;

b. The tabular presentation of adverse reaction data; and

c. The presentation of less common adverse events.

Consumer Safety

Although the draft guidance applies to labeling intended for health care professionals, we urge the FDA to consider that product labeling be made easily available to interested and motivated consumers on manufacturers' Web sites, in print and online versions of the *Physician's Desk Reference.*

The draft guidance provisions should protect consumer safety by ensuring that product labeling fully describes potentially serious adverse events.

FDA-approved labeling also provides the foundation for the brief summary portion of print direct-to-consumer advertisements.

Under FDA regulations, DTC print ads must state in a "brief summary" the side effects, warnings, precautions and contraindications featured in the product's approved labeling (21 CFR §202.1(e)).

BCBSA believes that both drug labeling and advertising should clearly communicate risk information so that it is understood by both consumers and health care professionals.

Under the draft guidance for product labeling, the adverse reactions section of the product labeling will result in a shorter, more accessible format. When this section is modified by manufacturers for use in the brief summary of DTC print ads, the brief summary will shorten accordingly. BCBSA urges the FDA to protect consumer safety by providing guidance to manufacturers so that a shorter brief summary does not minimize or omit potentially serious adverse events.

One approach would be for the FDA to require manufacturers to use the full amount of space for the shortened brief summary in print ads (i.e., one full page) but increase the type size. This approach would encourage and enable more consumers to read the brief summary of benefit and risk information.

Tabular Presentation of Adverse Reaction Data

The draft guidance states that "In general, there is no need to present less informative data in a table," and suggests that data from larger databases are not needed when placebo-controlled data are adequate.

BCBSA finds this language to be vague and is concerned that the exclusion of data from larger databases will not account for those adverse events reported voluntarily by individuals or health care professionals under the FDA's MedWatch Program. We recommend that the agency modify this language to include specific criteria to assist in the determination of when data from larger databases are not needed in the labeling.

Presentation of Less Common Events

BCBSA believes that the draft guidance provision instructing manufacturers to omit those adverse events "that would be expected to occur in the observed or studied population at a similar frequency absent drug therapy" needs clarification. While we support the FDA's effort to eliminate the "noise" of long and exhaustive lists of adverse events in drug labeling, "minor symptomatic complaints" experienced with sufficient frequency can rise to the level of a significant adverse event. BCBSA recommends that the agency establish a frequency threshold for the inclusion of such events in the labeling.

One approach would be to modify the draft guidance to instruct manufacturers to include minor adverse drug reactions that are greater than those reactions that occur with a placebo.

BCBSA appreciates the opportunity to comment on the draft guidance and looks forward to working with the agency on this issue. If you have any questions regarding our comments, please contact Christine Simmon at (202) 626-4838.

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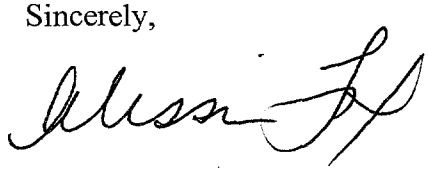

Alissa Fox
Executive Director
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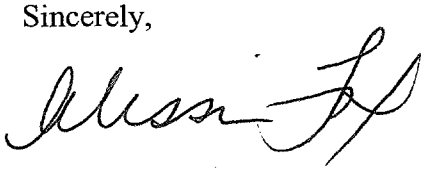

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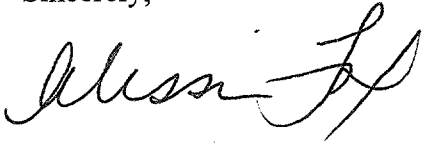

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